

Translation

PATENT COOPERATION TREATY

PCT/JP2004/000248



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3136WO0P	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/000248	International filing date (day/month/year) 15 January 2004 (15.01.2004)	Priority date (day/month/year) 17 January 2003 (17.01.2003)
International Patent Classification (IPC) or national classification and IPC G01N 33/50, 33/15, 33/53, 33/566, C12N 15/09, C07K 14/705, 16/28, C12Q 1/02, 1/68		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u>Disc 1</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 18 February 2004 (18.02.2004)	Date of completion of this report 16 November 2004 (16.11.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP04/000248

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 5-13, 37-44, 51-66, 71

because:

- ☒ the said international application, or the said claims Nos. 51-58
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The above claims encompass methods for treatment of the human body by therapy.

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-13, 37-44, 51-66, 71
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 5-13, 37-44, 51-66, 71.

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form	<input type="checkbox"/>	has not been furnished
	<input type="checkbox"/>	does not comply with the standard
the computer readable form	<input type="checkbox"/>	has not been furnished
	<input type="checkbox"/>	does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP04/000248

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 5-13, 37-44, 51-66, 71

because:

- ☒ the said international application, or the said claims Nos. 51-58 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The above claims encompass methods for treatment of the human body by therapy.

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-13, 37-44, 51-66, 71 are so unclear that no meaningful opinion could be formed (*specify*):

The above claims relate to compounds specified only by a screening method or functions, and it is not at all clear what specific compounds are, or are not, encompassed. The descriptions of the above claims, therefore, are significantly unclear.

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 5-13, 37-44, 51-66, 71.

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- | | | |
|----------------------------|--------------------------|-----------------------------------|
| the written form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:

As the applicant recognizes on page 2 of the specification, the sequences of 14723 receptors of a human and a mouse are publicly known, and so 14723 receptors cannot be "a special technical feature" or "a technical feature that expresses the contribution that each of the subject matters makes as a whole over the prior art."

The inventions of uses of 14723 receptors of a human or a mouse and those of 14723 receptors of a rat represented by SEQ ID NO.: 8 should appropriately be recognized as different from each other.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-4, 14-36, 45-50, 67-70, 72-77

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims	1-4, 16, 17, 20, 21, 24, 27, 28, 31, 34, 35, 45-50, 72-77	YES
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Claims	14, 15, 18, 19, 22, 23, 25, 26, 29, 30, 32, 33, 36, 67-70	NO
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Inventive step (IS)

Claims	1-4, 16, 17, 20, 21, 24, 27, 28, 31, 34, 35, 45-50	YES
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Claims	14, 15, 18, 19, 22, 23, 25, 26, 29, 30, 32, 33, 36, 67-70, 72-77	NO
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Industrial applicability (IA)

Claims	1-4, 14-36, 45-50, 67-70, 72-77	YES
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Claims		NO
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2. Citations and explanations (Rule 70.7)

Document 1: WO, 02-067868, A (Millennium Pharmaceuticals, Inc.), 6 September, 2002 (06.09.02)

The subject matters of claims 14, 15, 18, 19, 22, 23, 25, 26, 29, 30, 32, 33, 36 and 67-70 do not appear to be novel in view of document 1 cited in the ISR.

Document 1 describes GPCR12473 or polynucleotide to code for the said protein, describes that antibodies against 12473 can be used for diagnosis, prevention or treatment of diseases of a metabolic system including obesity and diabetes, and describes a screening method for medicinal drugs using 12473.

The subject matters of claims 72-77 do not appear to involve an inventive step in view of document 1 cited in the ISR.

Document 1 describes the amino-acid sequences and polynucleotide sequences of GPCR12473 of a human and a mouse. A person skilled in the art could have easily determined the sequences of 12473 of a rat by using the said publicly known sequences.

The subject matters of claims 1-4, 16, 17, 20, 21, 24, 27, 28, 31, 34, 35 and 45-50 do not appear to involve an inventive step in view of the documents cited in the ISR.

None of the documents cited in the ISR describes that ligands of 12473 are fatty acids or that 12473 can be used for diagnosis, prevention or treatment related to stress regulation or ACTH secretion, and those features are not obvious to a person skilled in the art.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".